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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/520,180

01/05/2005

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029650-162

7679

7590

08/06/2008

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EXAMINER

BOUCHELLE, LAURA A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

08/06/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/520,180	Applicant(s) NISHIKAWA ET AL.	
	Examiner LAURA A. BOUCHELLE	Art Unit 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 April 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-5,7-18,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7-18,21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 3, 4,5,21, 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross (US 4781691). Gross discloses a stepped needle comprising a liquid container 40 capable of holding liquid therein; an injection needle 10 having a puncture section 20 capable of piercing a living body; a proximal end section 14 having outside and inside diameters greater than said puncture section; a tapered section 18; a base body 12 supporting the needle, wherein the tapered section and the puncture section protrude from the base body. The tapered section 18 facilitates passage of the needle through the body tissue (Col. 4, lines 29) See Figs. 2 and 6. Gross further discloses that the injection needle has a liquid introducing needle section that can communicate with the liquid container. See Fig. 2. The outside diameter of the proximal end 14 is 0.64-1.3 mm, the outside diameter of the puncture section 16 is 0.46-0.64 mm, the length from the puncture section to the tapered section is 6.4-19 mm (Col. 3, line 63 – Col. 4, line 8). The puncture resistance is inherently 7gf or less since the device has the same size and shape as applicants. Gross discloses that the tapered section 18 facilitates passage of the needle through the body tissue (Col. 4, lines 30-33).
3. Claims 1 and 4 differ from Gross in calling for the length of the tapered section to be 1.5 to 10 mm, and the tapered section to possess an outer profile forming an angle ranging from 0.5

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degree to 1 degree and 20 minutes. Gross does not explicitly disclose these ranges, however Gross does disclose that the goal of the invention is to provide easy passage of the needle into human tissue. Gross achieves this goal by forming a tapered section in the needle having a small puncture resistance. Therefore, it would have been well within the skill of one of ordinary skill in the art to determine the optimal dimensions to achieve this goal. Applicant provides a graph in Fig. 8 of applicant's disclosure to provide support and criticality for the claimed ranges.

However, upon close consideration, it has been determined that this graph does not render the invention non-obvious. The graph does not show that the entire claimed range has been tested, nor does it disclose the dimensions of the needle which it is tested against. It is well known that a reduced angle will provide a smaller puncture resistance, and therefore, this graph proves nothing that is not already known. In other words, the use of the claimed dimensions does not show any unexpected results. Furthermore, the length of the tapered section is merely a function of the diameter of the smaller section, the diameter of the larger section, and the angle of the incline there between.

4. Claims 1, 4 further differ from Gross in calling for the total length of the needle to be 5 to 40 mm. It is known in the art to adjust the length of a needle to meet the requirements of the procedure in which it is to be used. The total length of the needle may be adjusted by lengthening or shortening the proximal section without affecting the puncture resistance or any other critical features of the device. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Gross to have any suitable length because it is beneficial to form a needle of a length to meet the requirements of the procedure.

5. Claims 7, 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of Hardt et al (US 5575778). Claim 7 differs from the teachings above in calling for the proximal end of the needle to include a second needle point. Hardt teaches a syringe having a needle 26 having a point at both the proximal and distal ends so that the proximal end of the needle can be inserted though the sealed septum of a container. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the needle of Gross to have a second point on the proximal end so that the needle can be inserted into a sealed container.

6. Claims 8-11, 14-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of Peery (US 7063681). These claims differ from the teachings above in calling for the puncture section to comprise a first facet having an angle of 8.5 degrees and a second facet having an angle of 18 degrees. Peery teaches a puncturing device having a puncture section 40 having a first facet having an angle of 5-45 degrees and a second facet having an angle of 10-60 degrees to provide minimal tissue trauma during insertion (Col. 4, lines 55-61; Col. 5, lines 7-10). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the device of Gross to include the two facets as taught by Peery to reduce tissue trauma upon insertion.

7. Claims 12, 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gross in view of Kaneko et al (US 6517523). Claims 12, 18 differ from the teachings above in calling for the cross-sectional angle formed between the ridges of the needle point to be 129 degrees.

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Kaneko teaches a needle comprising a pointed tip having a cross-sectional angle formed between the ridges to be 115-135 degrees to ensure that the resistance force at the time of sticking is as small as possible (Col. 6, lines 45-48). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the needle of Gross to include a cross-sectional angle of 129 degrees as taught by Kaneko to ensure that the resistance force at the time of sticking is as small as possible.

Response to Arguments

8. Applicant's arguments filed 4/24/08 have been fully considered but they are not persuasive. Applicant argues that the device of Gross discloses a needle that is longer than the instant invention. It is well known in the art to use needles of varying lengths to meet the requirements of the procedure. The length of the proximal portion may be lengthened or shortened without changing the dimensions of the distal puncture portion. It would have been obvious to use the teachings of Gross with regards to the puncture section on any length of needle.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LAURA A. BOUCHELLE whose telephone number is (571)272-2125. The examiner can normally be reached on Monday-Friday 8-4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas Lucchesi can be reached on 517-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura A Bouchelle
Examiner
Art Unit 3763

/L. A. B./
Examiner, Art Unit 3763

/Nicholas D Lucchesi/
Supervisory Patent Examiner, Art Unit 3763

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